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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/706,325	11/03/2000	Juan M. Zapata	P-LJ 4453	6212

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/706,325	ZAPATA ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 70-72,75,77,79-83,87-89 and 93-98 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 70,71,75,77,79-83,87-89 and 93-98 is/are rejected.

7)☒ Claim(s) 72 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claim 72, 87, 93 and 96 have been amended. Claims 9-11 and 68 have been canceled. Claims 70-72, 75, 77, 79-83, 87-89, 93-98 are pending and under consideration.

2. After review and reconsideration, the finality of the Office action mailed July 6, 2004 is withdrawn.

3. Sections of title 35, U.S. Code, not found in this action, can be found in a previous action.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 70, 7182, 88, 94 and 97 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 70 embodies the antibody of claim 72 wherein said TNF-family receptor is TNF-R2, said TRAF protein is human TRAF6 and said TRAF-associated protein is I-TRAF. Claim 71 embodies the antibody of claim 72 wherein said TNF family receptor is CD40, said TRAF protein is human TRAF2 and said TRAF associated protein is I-TRAF. The specification as filed provides a written description of antibody which increase or decrease the biological activity of an invention TRBD protein such as TNF receptor family binding, TRAF protein binding, TRAF associated protein binding, NF-kB modulation, JNK modulation, etc (page 52, lines 15-31).. This fails to provide support for the specific limitations of claims 70 and 71 which were not recited as part of the antibodies modulating activities in the specification or claims as filed.

Claims 82, 88, 94 and 97 are drawn to a cell line producing the monoclonal antibody of claims 81, 87, 93 and 96, respectively. The specification as filed contemplates only hybridomas

(page 51, line 10). However, the claims encompass prokaryote and eukaryote cell lines which recombinantly produce the claimed antibodies, which is larger than scope than a hybridoma cell line.

One of skill in the art would reasonable conclude that applicant was not in possession of the above claimed inventions at the time of filing.

6. Claims 75, 77, 80, 81, 83, 87, 89, 96 and 98 rejected under 35 U.S.C. 103(a) as being unpatentable over Comb et al (U.S. 6,441,140) in view of Brodeur et al (Journal of Biological Chemistry, 1997, Vol. 272, pp. 19777-19784).

Combs et al teach monoclonal and polyclonal antibodies which recognize degenerate motifs in a context-independent fashion (column 3, lines 44-50). Combs et al teach that said antibodies can be used to identify previously unknown substrates of a known enzyme by using the motif-specific context independent antibodies raised against motifs common to other substrates of said enzyme (column 4, lines 1-5). Combs et al do no specifically teach antibodies which bind to a context-independent motif on SEQ ID NO:12 or 25.

Brodeur et al teach the motif of PXQX(T/S) as a TRAF recognition site (page 19782, column 1, lines 2-6).

It would have been prima facie obvious at the time the invention was made to make monoclonal and polyclonal antibodies which specifically bind to the PXQX(T/S) motif by substituting the PXQX(T/S) motif for the alternative degenerate motifs taught by Combs et al, such as the 14-3-3 motif (column 3, lines 53-57). One of skill in the art would have been motivated to do so by the teachings of Brodeur et al on the degenerate motif found in TRAF recognition sites. One of skill in the art would be motivated to find other proteins which also comprised said TRAF recognitions sites. The resulting antibodies would bind the instant SEQ ID NO:12 and 25 which have the PXQX(T/S) motif at residues 33-37 and 30-34, respectively.

7. Claims 75, 79, 81 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagai et al (FEBS Letters, 1997, Vol. 418, pp. 23-26, cited in a previous action) and Campbell (Monoclonal Antibody Technology, 1985, pages 1-32).

Nagari et al teach an amino acid sequence, SPOP, consisting of all of residues 1-132 of SEQ ID NO:24. Nagari et al produce the recombinant antibody using a "HA" tag and detect said tagged protein by means of an anti-HA antibody. Nagari et al do not teach an antibody which binds to the SPOP protein without the HA tag.

Campbell teaches that the potential of monoclonal antibodies in the basic research is considerable because they can resolve a single protein from a complex mixture or indeed a single epitope responsible for a specific function of a complex macromolecule. Campbell also teaches that it is customary now for any group working on a macromolecule to both clone the genes coding for it ad make monoclonal antibodies to it (sometimes without a clear objective for their application)" (page 29, section "Basic research" in particular).

It would have been prima facie obvious at the time the invention was made to make a monoclonal antibody to SPOP. One of skill in the art would have been motivated to do so by the teachings of Campbell et al and because it would enable one of skill in the art to detect the natural protein without need for the HA tag.

8. Claims 75, 79, 81, 83 and 93are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagai et al (FEBS Letters, 1997, Vol. 418, pp. 23-26) and Campbell (Monoclonal Antibody Technology, 1985, pages 1-32) as applied to claims 75, 79, 81 and 93 above, and further in view of Paul (Fundamental Immunology, 1993, text, pages 460-461).

Claim 83 embodies the antibody of claim 75 wherein said antibody is a polyclonal antibody. The combination of Nagari et al and Campbell render obvious the instant claims with respect to a monoclonal antibody. The combination does not teach a polyclonal antibody.

Paul teaches that advantages of polyclonal antibodies over monoclonal antibodies in certain situations where multi-valency is important (page 460, second column, third paragraph under the heading "Polyclonal Versus Monoclonal Antibodies").

It would have been prima facie obvious at the time the claimed invention was made to make a polyclonal antibody which would directly bind to the SPOP protein of Nagai et al. One of skill in the art would have been motivated to do so by the teachings of Paul on the advantages of polyclonal antibodies, and because one of skill in the art would want to be able to detect the SPOP protein in the natural state without requiring the HA tag.

9. Claim 72 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. All other rejections and objections as set forth or maintained in a previous Office action are withdrawn.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
7/28/2005

Karen A. Canella
KAREN A. CANELLA PH.D
PRIMARY EXAMINER